BODY FLUID FLOW CONTROL DEVICE

This is a continuing application of U.S. Patent Application No. 09/397,218, filed September 16, 1999, which is a continuing application of U.S. Patent Application No. 08/931,552, filed September 6, 1997, and issued as U.S. Patent No. 5,954,766, which disclosures of the above are incorporated herein by reference.

BACKGROUND OF THE INVENTION

The field of the present invention is valve mechanisms for use in the human body.

Valves play an important role in a number of bodily functions. One such physiologic valve is in the urinary tract. Valve failure in this system leads to urinary incontinence, a significant health issue. Urinary incontinence is estimated to affect some ten million Americans. The full extent of this problem is unknown because less than half of affected adults are believed to actually seek medical attention.

Devices are available to assist in the control of urinary incontinence. Such devices include external valves, valves extending throughout the lower urinary tract and into the bladder, devices extending through long portions of the urethra and implanted protheses as well as injected bulking agents which support the urethral sphincter to enhance operation. Such devices are often inconvenient, uncomfortable and/or require surgical insertion. Other devices are considered overly

intrusive.

Native valves are also found in cardiovascular systems. In veins, native venous valves promote one-way flow toward the heart from the periphery. Diseases exist such as venous thrombosis and thrombophlebitis which can render native venous valves incompetent, resulting in edema. Replacement of these artificial valves with artificial ones could provide substantial health benefits.

The pulmonic valve associated with the heart is yet another native flow control mechanism which can exhibit incompetence either congenitally, through disease or iatrogenically due to treatment of pulmonary stenosis. A one-way valve positioned distal to the native pulmonic valve within the pulmonary artery could be of substantial benefit in overcoming this problem.

SUMMARY OF THE INVENTION

The present invention is directed to a body fluid flow control device which includes an ability to seal about the device in the fluid passageway, a placement and retention format for the device and a valve body capable of either or both a pressure threshold for operation and a one-way flow restriction. The valve body preferably end bulk resilience and a passage therethrough which is closed by that bulk resilience. This may be defined by an elastomeric or other polymeric body with a passage therethrough cut without the removal of material. A single slit, a cross or a star shaped cut are included among the possibilities. One-way flow may be accomplished through a flap or other inhibitor physically impeding flow in one direction or by a configuration of the valve to employ passage pressure to prevent opening.

In a separate aspect of the present invention, such devices as contemplated above are combined with mechanisms to assist in transforming the state of the device from insertion to anchoring.

Accordingly, it is a principal object of the present invention to provide a flow control device for the human body such as for urinary, venous or pulmonic placement. Other and further objects and advantages may appear hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a first flow control device.

Figure 2 is a cross-sectional side view of the device of Figure 1.

Figure 3 is a cross-sectional side view of a second flow control device.

Figure 4 is an end view of a third fluid flow control device.

Figure 5 is a cross-sectional view taken along line 5-5 of Figure 4.

Figure 6 is an end view of yet another fluid flow control device.

Figure 7 is a cross-sectional view taken along line 7-7 of Figure 6.

Figure 8 is a cross-sectional view of yet another fluid flow control device.

Figure 9 is a cross-sectional view of yet another fluid flow control device.

Figure 10 is a cross-sectional view of yet another fluid flow control device.

Figure 11 is a cross-sectional view of the device of Figure 10 with a balloon expander positioned within the device.

Figure 12 is a cross-sectional side view of an insertion tool with a fluid flow control device in place.

Figure 13 is a prospective view of another frame.

Figure 14 is a prospective view of yet another frame.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figures 1 and 2 illustrate a first fluid flow control device capable of one-way flow, the sealing of a body passageway and pressure actuation. The device includes a resilient seal 20 which, in this first embodiment, includes a cylindrical elastomeric or, more generically, polymeric material capable of sealing within the interior of a body duct or passageway. This resilient seal is shown in this embodiment to be cylindrical but may be tapered through a portion thereof. In either instance, the seal has a substantially circular cross section to fit within the body duct or passageway.

To one end of the seal 20, a valve support 22 extends inwardly from an attachment to the valve body. This valve support 22 preferably provides a barrier to flow through the resilient seal. The support 22 is conveniently formed as one piece with the seal 20.

A valve body 24 is attached to the valve support 22 about the outer periphery of the body 24. The valve body 24 is also of polymeric material and may be most conveniently formed as one piece with the seal 20 and the valve support 22. The body 24 is shown in this first embodiment to define a passage 26 which is shown to be a single slit. The slit 26 extends longitudinally through the valve body. The body of the valve being polymeric and resilient is able to provide bulk resilience to maintain its natural state. As the slit 26 is preferably manufactured without removal of material from the valve body 24, the resilience of the body closes the slit 26 so that no flow can occur. Through empirical testing, an appropriate size of the slit 26 and overall body size and shape of the valve body 24 will define a threshold

pressure which may be applied to one end of the valve to cause the slit 26 to open. For purposes of urinary tract control, this opening pressure should be in the range of about 0.2 psi to 3.0 psi. For intervascular placement, the threshold should be from about 0.005 psi to 1.0 psi.

The valve body 24 acts in this embodiment as a one-way valve because of the substantially parallel sides to either side of the slit 26. In the event that flow builds up on the side of the valve with the extending substantially parallel sides 28, the pressure will not only build up at the slit 26, it will also build up on the parallel sides 28 as well. The pressure on the sides will prevent the slit from opening.

A frame, generally designated 30, is located within the peripheral resilient seal 20. This frame 30 is contemplated to be a metallic member having an expanded metal cylinder 32 defined by longitudinally extending elements 34. In this instance, the longitudinally extending elements 34 are interconnected as one construction so as to form the expanded metal cylinder.

The resilient seal forming the peripheral element about the frame 30 to define a seal with the duct or passageway in which the device is placed may be affixed to the frame 30 by any number of conventional means. For example, the frame 30 may be bonded to the resilient seal 20. The resilient seal 20 may be formed through injection molding, blow molding, insertion molding or the like with the frame in place within the mold such that the frame 30 becomes embedded within the seal 20. There may be a physical interlocking through the use of an inwardly extending flange on the open end of the resilient seal 20 to physically retain the frame 30.

The frame 30, being of expanded metal, is capable of being easily stretched to expand from a stable first state to a stable expanded state. The first state, referred to as the insertion state, is contemplated with the overall diameter of the frame 30 and the surrounding resilient seal 20 exhibiting a first diameter. With the frame 30 expanded to what may be termed an anchor state, the resilient seal 20 also expands. In the expanded state, the overall device is intended to fit with interference in the duct or passage. Before expansion, easy insertion is contemplated with clearance.

The construction of this first embodiment provides for the valve support 22 to extend longitudinally in a cylindrical element 36 from an inwardly extending disk element 38. A further inwardly extending disk element 40 extends to the valve body 24. The employment of the cylindrical element 36 between these disk elements 38 and 40 is intended to isolate the valve body 24 from the displacement of the resilient seal 20 as the frame is expanded from an insertion state to an anchor state. Distortion of the valve which may result in a change in the threshold pressure to open the valve may be avoided.

Looking to Figure 3, a similar view to that of Figure 2 illustrates a second embodiment. This embodiment differs from the prior embodiment in the redirection of the valve body 24 at the disk 40. With that redirection, the valve body 24 is positioned to face in the opposite direction. In this way, the one-way feature operates to provide flow in the opposite direction relative to the frame 30 and resilient seal 20.

Turning to Figures 4 and 5, another embodiment is illustrated. Identical

reference numbers are applied to those of the first embodiment to similar structures and functional elements. Presenting a more quantitative description, the wall thickness of the elastomeric polymer defining the resilient seal 20, valve support 22 and valve body 24 is contemplated to be between approximately .005" and .050". The width of the slit is approximately .024" while the outside diameter of the resilient seal 20 is approximately .349". The length of this element is contemplated to be approximately .60". The frame is cylindrical with an OD in the insertion state of approximately .329", a length of approximately .304" and a thickness of approximately .005" to .015". This member is preferably of stainless steel or nitinol. The metallic member in this and each other embodiment is contemplated to be substantially nonreactive with body fluids and the body itself or coated with such a nonreactive material. Other dimensions can also be manufactured depending on the size of the placement.

Turning to the embodiment of Figures 6 and 7, substantially the same device is illustrated as in the prior embodiment. Again, the correspondence of reference numerals reflect similar structures and functional features. This device has an added flap 42 overlying the passage 26. The flap 42 is attached by adhesive, bonding or other conventional procedure. The passage 26 may again be a slit as previously described so as to provide a threshold pressure level before opening. If a passageway is presented instead, the device will simply act as a one-way valve.

Turning to Figure 8, a different overall exterior configuration is presented as well as a different frame. A polymeric resilient seal 44 is shown to extend over a

frame, generally designated 46. The frame 46 includes longitudinally extending elements 48. The elements 48 extend from a conically shaped portion 50 of the frame 46. This conically shaped portion 50 is truncated to provide a wide passageway 52 for operation of the valving mechanism. The resilient seal 44 forms a skirt which extends inwardly to a valve support 54 which is located about the truncated conical portion 50. The valve support 54 and the resilient seal 44 are preferably of the same piece of material. A valve body 56 extends across the passageway 52 in an appropriate thickness to provide the appropriate bulk resilience to accommodate a threshold opening pressure. A passage 58, shown here to be a slit extends through the valve body 56.

Turning to Figure 9, a device similar to that of Figure 8 is disclosed. Common reference numerals indicate similar elements and functional features. The resilient seal 44 extends over the longitudinally extending elements as a skirt with the ends of the elements 48 extending outwardly therefrom. A truncated somewhat conical portion 50 actually forming a dome shape extends to a passageway 52. The valve support 54 covers this portion 50. A truncated cone shaped element 60 forms a further part of the valve. It may be part of the same piece of material as the resilient seal 44 and valve support 54. A valve body 62 is shown to be a cylindrical element with a passage 58, shown here to be slits in the form of a cross or star extending longitudinally therethrough.

The length of the valve body 62 establishes that the passage 64 will operate only in expansion and not through bending of the components. Thus, a substantially greater threshold level of pressure is anticipated for this configuration.

Figure 10 illustrates yet another fluid flow control device. This device includes a resilient seal 66 in the form of a cuff extending about one end of the periphery of the device. The frame 68 is generally on the outside of the valve with longitudinally extending elements 70 extending into the cuff 66. The valve support 72 extends within the frame 68 to a valve body 74 which forms a disk element with a slit 78 therethrough. The frame 68 includes a section in the form of a solid disk 80 with a passageway 82 therethrough. The passageway 82 is substantially larger than the slit 78 in order that it not interfere with the operation thereof. The solid disk 80 also acts to tie together the longitudinally extending element 70 extending out to the cuff 66.

A variety of slits or other mechanisms may be employed to achieve flow through a passage above a preestablished threshold pressure. With thin membranes, a slit or multiple crossed slits can employ a bending component to achieve flow. The bulk resilience is employed more in bending than in radial compression away from the cut or cuts. With longer passageways, radial compression outwardly from the passage provides the controlling mechanism. The thickness of the resilient seal as measured laterally of the slit can be of importance in one-way flow operation. With a thin lateral wall thickness, the pressure surrounding the valve can prevent its opening. Thus, flow would only occur from the side of the valve where pressure cannot accumulate and prevent its opening.

The frame is to be capable of two states, an insertion state and an anchoring state. The anchoring state is larger than the insertion state by the laterally extending resilient elements being outwardly of the insertion position of these

elements when they are in the anchor state.

To achieve these two states, a number of mechanisms may be employed. First, a malleable material can be used. Because the passageways and ducts within the body are quite resilient, large changes in diameter are not required. Consequently, almost any metal is capable of sufficient malleability, particularly if it is employed in an expanded metal state, for example. Reference is made to the embodiment of Figures 1 and 2. The choice of metals can become more dependent upon satisfying environmental needs within the body.

Another mechanism which may be employed to accommodate this two-state requirement is spring resilience. The insertion state can be achieved through a preconstraint of the longitudinally extending elements within the elastic range of these elements. Once positioned, the elements can be released to expand into an anchoring state. Constraining tubes or pull wires may achieve the initial insertion state.

Another mechanism which may be used to accomplish both the insertion and the anchor states of the frame is the heat recovery of materials available with alloys such as certain nickel titanium alloys. Preferably the transition temperature of such devices is below body temperature. Under these circumstances, a cool device can be positioned and allowed to attain ambient temperature. The unrecovered state of the frame would be in the insertion position with the longitudinally extending elements in a radially contracted position. Upon recovery, the frame would expand. Another use of this material may be through a heating of the device above body temperature with a recovery temperature zone above that of normal body

temperature but below a temperature which may cause burning. The device might be heated electrically or through the modulation of a field.

To accomplish a transition from the insertion state to the anchoring state, a variety of devices may be employed. An elongate expander is illustrated in Figure 11. A balloon 84 is presented at the end of an elongate passage 86 through which pressure may be transmitted. The fluid flow control device can be inserted on the mechanism making up the passage 86 and balloon 84. When in position, the balloon 84 is expanded through the application of pressure to the accessible end of the passage 86. The malleable longitudinally extending elements are bent beyond their yield point into an interfering engagement with the wall of the passageway in the body.

Another mechanism for providing an elongate expander and insertion tool is illustrated in Figure 12. The device includes an outer sheath 88 into which is positioned a fluid flow control device which has longitudinally extending elements that are of spring material. The elements are bent such that the frame is radially constricted. The size of the sheath inner diameter is such that the spring elements are not bent to the point that they exceed the elastic limit. A ram 90 extends into the sheath 88 to force the fluid flow control device from the end of the sheath. As the device is released from the sheath 88, it will naturally expand to the anchored state. This same mechanism may be employed with any of the devices for placement regardless of whether the mechanism for expansion is deformation, heat recovery or resilience. Naturally, the ram 90 can accommodate a heating element or balloon mechanism depending upon the appropriate need.

Finally, Figures 13 and 14 illustrate two additional forms of the frame which may be employed in place of one of the other frames disclosed. The frame may form a complete cylinder or a rolled sheet 92 as in Figure 13. A frame which is another alternative is seen in Figure 14. A longitudinally extending element 94 is formed into a coil. These devices may be of heat recoverable material so as to form an insertion state and an anchor state or be of spring material constrained to a reduced diameter for insertion.

Considering the use of these devices, the thresholds are selected with the appropriate pressures in mind. With incontinence, the threshold pressure is high enough to prevent leakage as normal pressure builds in the bladder. When the bladder is to be voided, abdominal pressure is used. The threshold pressure is also low enough that the abdominal pressure will overcome the resistance and allow flow. Where placement is in the cardiovascular system, minimum resistance to flow in one direction may designed into the valve. In this application, however, substantial resistance to flow is designed into the valve to eliminate flow in one direction for all pressures contemplated.

Accordingly, a number of improved devices for providing body fluid flow control are disclosed. While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art that many more modifications are possible without departing from the inventive concepts herein. The invention, therefore is not to be restricted except in the spirit of the appended claims.